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09/716,486	11/20/2000	Chet M. Crump	BAL-66-CON	8937

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EXAMINER

WEISS JR, JOSEPH FRANCIS

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3743

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 22

Application Number: 09/716,486

Filing Date: November 20, 2000

Appellant(s): CRUMP ET AL.

Mr. Neal P. Pierotti
For Appellant

EXAMINER'S ANSWER

MAILED

MAR - 4 2004

GROUP 3700

This is in response to the appeal brief filed 4 Feb 04.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement that the claims 1-12 stand or fall together is correct.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5354267	Niermann et al.	10-1994
5775325	Russo	07-1998
5370610	Reynolds	12-1994
5005568	Loescher et al.	04-1991

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-7, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann et al (US 5354267) in view of Russo (US 5775325).

In regards to claim 1, Niermann discloses a respiratory suction apparatus (10) comprising a suction catheter (18) for removing fluids from a respiratory tract of a patient by insertion of the distal end (see fig 1, portion of 18 within elements 35 & 75) of the catheter into a patient's respiratory tract and withdrawal of the distal end of the catheter through a portion of the tract while applying negative pressure to the lumen of the catheter (see the background & summary of the invention); a protective sleeve (20) surrounding a proximal longitudinal portion of the catheter; a distal adapter (16) configured for fluid communication with a manifold (14) of a patient's artificial airway; a collar (32) disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from the manifold, the catheter and the collar defining a substantially uniform cylindrical space around the distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter (see fig 2 and supporting text); and a valve device (74) configured in the adapter to

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substantially isolate the catheter from the manifold upon withdrawing the distal portion of the suction catheter into the adapter and applying suction through the catheter lumen (See fig 6 & supporting text) said valve device being opened by advancement of said suction catheter through said valve device (col. 4 lines 40-55) and a lavage port (40), but does not explicitly disclose the lavage port positioned to be in fluid communication with the annular space between the suction catheter and the adaptor when the suction catheter is present. However, Russo disclose such (See figs 5 & 6, lavage port 37/38). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Russo and used them with the device of Niermann. The suggestion/motivation for doing so would have been to permit suction catheter & adapter cleaning and sanitization while the device is in use. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 2, Niermann discloses the valve device as comprising a flap valve (note the flaps of element 74) disposed distal to a distal end of the collar.

In regards to claim 3, the flaps of Niermann are seated against the collar by dint of being attached to element 62, which is seated against the collar (32) throughout the operation, thus to include when the negative pressure is applied.

In regards to claim 4, the flaps of Niermann are fully capable of seating against the distal end of the suction catheter upon application of suction through the catheter lumen.

In regards to claim 5, Niermann substantially discloses the instant application's claimed invention to include a cleaning enclosure defined within the adapter (interior as defined by 62) wherein the distal end of the catheter is exposed to cleaning liquids, but does not explicitly disclose exposure to turbulent air flow during the cleaning procedure. However by use of suction and dint of the presence of gas in the cleaning enclosure, and the multiple openings present in the distal end of the catheter one of ordinary skill in the art would appreciate that the device of Niermann generates a turbulent airflow at the distal end when suction is applied.

In regards to claim 6, Niermann substantially disclose the claimed invention to include being capable of permitting turbulent air flow to originate from the slit/aperture of the valve. (When 32 is set in a position that would permit simultaneous fluid communication with both the valve and line 44 via alignment with 36)

In regards to claim 7, Niermann discloses the valve device (74) seated against the distal end of the collar. (See the interface between 74 & 32 by dint of element 62).

In regards to claim 10, the device of Niermann substantially discloses the instantly claimed invention as noted above in regards to the rejections to claims 1 & 5,

and furthermore, discloses a means that is fully capable of producing a predetermined rate of airflow to the enclosure responsive to negative pressure in the catheter (flow generator attachable to 24 that generates flow 25), the catheter being protected by the sleeve, adapter and enclosure from environmental contamination, the valve including a flap and a hinge (point of direct interface of either flap with the adapter) and where the flap is fully capable of occluding the catheter responsive to a pressure differential between the flap and the enclosure.

In regards to claim 11, the device of Niermann is fully capable of and does disclose in light of the understanding of one of ordinary skill in the art that the air flow rate in the device is responsive to negative pressure, i.e. flow is known to follow negative sloped pressure gradients, the greater/steeper the gradient the greater the flow rate induced by the negative pressure introduced.

2. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann & Russo as applied to claim 6 above, and further in view of Reynolds (US 5370610).

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a filter to filter airflow provided to the cleaning enclosure. However, Reynolds disclose such (# 64). The references are analogous since they are from the same field of endeavor, the medical arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Reynolds and used them with the suggested device. The suggestion/motivation for doing so would have been to reduce the possibility of infecting the patient by filtering out bacteria (See Reynolds col. 9 line

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50). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann, Russo & Reynolds as applied to claim 8 above, and further in view of Loescher et al (US 5005568).

The suggested device substantially discloses the instant application's claimed invention, to include a valved opening (62 of Reynolds) but does not explicitly disclose the use of a valve in conjunction with the filter in the same opening. However, Loescher discloses such (See the filter/valve combination). The references are analogous since they are from the same field of endeavor, the medical/respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Loescher and used them with the suggested device. The suggestion/motivation for doing so would have been to have better control over the air being permitted to enter the medical device's interior. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of

design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann & Russo as applied to claim 11 above, and further in view of Reynolds.

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose a filtered opening to ambient in the body of the cleaning enclosure. However, Reynolds disclose such (See # 64). The references are analogous since they are from the same field of endeavor, the medical arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Reynolds and used them with the suggested device. The suggestion/motivation for doing so would have been to reduce possible bacterial contamination during use/operation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

(11) Response to Argument

For the above reasons, it is believed that the rejections should be sustained.

Appellant presents three sets of arguments (A-C) all directed to the main 103 obviousness rejection based upon the combination of Niermann in view of Russo. The basic thrust of the three arguments is as follows:

A-The references fail to provide the proper motivation by dint of teach away from being combinable to result in instantly claimed invention.

B-In the alternative, even if combined they do not teach the claimed invention.

C-The examiner is using appellant's written description to provide the motivation to combine, i.e. the motivation used is impermissible hindsight.

All three of these arguments fail for the following reasons. The examiner has never expressly stated that the combination required the wholesale lifting of the invention of Russo in its entirety to cure the silence of Niermann regarding Niermann's obviation of appellant's invention as appellant's arguments assume. This rejection, like all rejections was written on the premise of a combination of the teachings as viewed by one of ordinary skill in the art and not upon an actual physical attempt to combine the inventions. Furthermore, the examiner never made such statements on the record, instead the examiner used the teaching of Russo to provide the motivation to use Niermann in the arrangement of "the lavage port positioned to be in fluid communication with the annular space between the suction catheter and the adaptor when the suction catheter is present."

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For clarification purposes the examiner direct's appellant and the board to Niermann, which uses a ball valve (16) that has a "T" connection that Niermann discusses three of four positions such a "T" connection ball valve would have. Please note that the valve possesses no illustrated or disclosed physical impediments to placing the valve in a fourth position. The fourth position that is not discussed by Niermann would be the same as the positioning illustrated in Figure 1 to permit the longitudinal positioning of the catheter (The top of the "T"), but the stem of the "T" would be in line and fluid communication with the lavage port (40). The end result of this positioning would be the lavage port positioned to be in fluid communication with the annular space between the suction catheter and the adaptor when the suction catheter is present. Having Niermann as a 102 or a 103 stand alone type rejection was considered untenable in light of the fact that Niermann focused on three of the four positions and while one of ordinary skill in the art would reasonably conclude that the structure was fully capable of achieving such an end, there was no express motivation to achieve this arrangement the fourth position of the Niermann device was capable of achieving.

Hence, Russo was used to provide a motivation for achieving this operational/structural end state/relationship to motivate one of ordinary skill in turning Niermann's valve two this fourth position. The logic was as follows:

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However, Russo disclose such (See figs 5 & 6, lavage port 37/38). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Russo and used them with the device of Niermann. The suggestion/motivation for doing so would have been to permit suction catheter & adapter cleaning and sanitization while the device is in use.

The above explication of the rejection debunks all of appellant's arguments as follows:

A-Niermann does not need Russo to teach the bald structural elements of appellant's claimed invention, but only sufficient motivation to use his invention to meet the operational/structural relationship claimed, which Russo provides as noted by the rejection.

B-Russo provides the motivation for using the device of Niermann in the manner appellant claims argues is the novel and non-obvious operational inventive relationship.

C-As Russo provides this motivation and Russo is prior art available to one of ordinary skill in the art, as well as to the examiner, the motivation cannot be considered to have come from appellant's written description and hence cannot be impermissible hindsight.

→ ?

Respectfully submitted,

Joseph F Weiss Jr.

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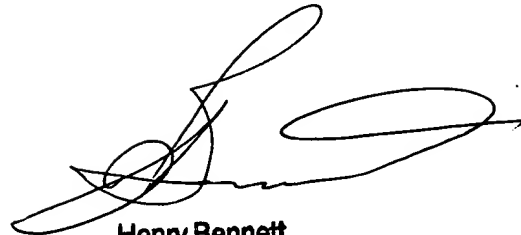
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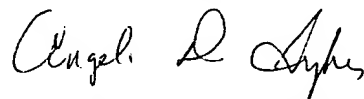
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